

REMARKS

This amendment is responsive to the Office Action mailed October 19, 2005 and to the Communication mailed April 11, 2006, in connection with the above-identified patent application. In the Action, claim 1 and 6-11 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens. Claims 3 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens. Claim 4 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,147,315 to Weber. Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Weber and further in view of U.S. Patent No. 5,843,051 to Adams, et al. Claims 24, 27, 28, 41, 42, and 43 were discussed at the bottom of page 4 of the Office Action but were not rejected explicitly. As a courtesy, applicant's representative contacted the Examiner for clarification of this portion of the Office Action. Apparently, the Examiner intended to reject claims 24, 27, 28, 41, 42, and 43 under 35 U.S.C. § 103(a) over Stevens. For purposes of helping the Office to advance prosecution, rather than requesting a Supplemental Action, and as a courtesy to the Examiner, applicant will treat the Action as if the rejections were indeed made. Claims 44-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Murphy-Chutorian. In this rejection, it is to be noted that the Examiner misidentified the Murphy-Chutorian patent in the Action. Again, in order to help the Office by facilitating the advancement of prosecution rather than requesting a Supplemental Action, and as a courtesy to the Examiner, applicant's representative contacted the Examiner for further clarification. The Examiner noted that the Action should have cited U.S. Patent No. 4,832,023 to Murphy-Chutorian. The instant amendment will treat this rejection in the Action accordingly although it is not indicated as so in the record to this point.

THE OFFICE ACTION IS INCOMPLETE

As noted above, the Examiner discussed claims 24, 27, 28, 41, 42, and 43 at the bottom of page 4 and at the top of page 5 of the Office Action. However, it is

not clear from the record whether the Examiner intended to reject those claims and, if so, under which statutory section and, further, in view of which one or more prior art teachings. In the paragraph beginning with "as to claims 24, 27, 28, 41, 42, and 43," the Examiner discusses the Stevens patent. No other prior art teachings are discussed in that paragraph.

Applicant considers the Office Action, therefore, to be incomplete. The Communication mailed from the Office on April 11, 2006 included some comments from the Examiner but no clarification(s) on the above were provided. However, again, for purposes of expediting prosecution of this application and for reasons given above, applicant will consider the comments made by the Examiner on pages 4 and 5 of the Action to be a rejection of claim 24, 27, 28, 41, 42, and 43 as being rejected under 35 U.S.C. § 103(a) and unpatentable over U.S. Patent No. 5,972,143.

Next, the Office Action is incomplete because the Examiner has not properly identified the secondary prior art reference in connection with the rejection of claims 44-51 under 35 U.S.C. § 103(a) as being unpatentable over Stevens in view of Murphy-Chutorian. Applicant's representative requested clarification from the Examiner regarding the proper patent number citation of the Murphy-Chutorian reference. The Examiner indicated by telephone that the rejection of claims 44-51 was to cite U.S. Patent No. 4,832,023 to Murphy-Chutorian rather than U.S. Patent No. 5,972,143. The Communication mailed from the Office on April 11, 2006 included some comments from the Examiner but no clarification(s) on the above were provided. Again, for purposes indicated above including expediting prosecution in this matter and as a courtesy to the Examiner, this amendment will address the rejection as having been made using the proper patent number.

THE ART REJECTIONS

The Present Application:

A first embodiment of the invention is directed to a reinforced catheter apparatus (claims 1, 3-11, and 41-51) and a second embodiment of the invention is

directed to a reinforced catheter stock for manufacturing reinforced catheters (claims 24 and 26-28). The first and second embodiments of the invention forming the instant application are the subject of this prosecution and of the instant amendment. A third embodiment of the invention is directed to a method of manufacturing multiple reinforced catheters (claims 12-23), and a method of manufacturing a reinforced catheter stock (claims 29-33), and a fourth embodiment is directed to an apparatus for manufacturing the reinforced catheter stock (claims 34-40). The third and fourth embodiments of the invention in the instant application are not the subject of this prosecution or amendment and have been previously withdrawn.

As noted above, a first embodiment of the invention is directed to a reinforced catheter apparatus. Essentially, the apparatus includes an elongate tubular member carrying a continuous coil reinforcement member thereon from end to end. First and second layers of outer coatings are disposed onto the tubular member and coil reinforcement in turn so that the first material forms a first layer thereon and the second material forms a second layer on the first material. The inner first material is softer than the outer second material. A portion of the second outer coating is ground away to form a flexible distal tip portion of the catheter. The coil reinforcement member is present in the distal tip portion of the catheter between the tubular member and the inner first material.

The reinforced catheter apparatus 68 is shown in Figure 4b as amended and is described in the specification, particularly at page 14. The reinforced catheter 68 comprises an elongate flexible tubular member 51 defining a lumen of the catheter, a continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51, a first flexible outer coating 58 covering the coil reinforcement member 54, and a second flexible outer coating 62 covering a first portion 74 of the first outer coating 58. The elongate flexible tubular member 51 defining the lumen of the catheter has a first end defining a proximal end 69 of the catheter, and a second end defining a distal end 67 of the catheter. The continuous coil reinforcement member 54 (Fig. 2c) carried on the elongate flexible tubular member 51 extends from the proximal

end 69 of the catheter to the distal end 67 of the catheter. The first outer coating 58 covers the coil reinforcement member 54 and the tubular member 51 substantially entirely between the proximal end 69 of the catheter and the distal end 67 of the catheter. The second flexible outer coating 62 covers a first portion 74 of the first outer coating 58 between a first transition area 73 of the catheter and the proximal end 69 of the catheter. A second portion 72 of the first outer coating 58 is uncovered by the second outer coating 62 and defines a flexible tip 72 of the catheter. Lastly, in the first preferred embodiment, the first outer coating 58 is softer than the second outer coating 62.

In another form, a reinforced catheter 68 is provided comprising an elongate flexible tubular member 51 defining a lumen of the catheter, the tubular member 51 having a first end defining a proximal end 69 of the catheter and a second end defining a distal end 67 of the catheter. A first flexible outer coating 58 covers the tubular member 51 fully between the proximal end 69 of the catheter to the distal end 67 of the catheter. A second flexible outer coating 62 covers a first portion 74 of the first outer coating 58 with a second portion 72 of the first outer coating 58 being uncovered by the second outer coating 62 and defining a flexible distal tip 67 of the catheter. The first coating 58 is softer than the second coating 62. A coil reinforcement member 54 (Fig. 2c) is carried on the elongate flexible tubular member 51 and is disposed at the distal tip 67 of the catheter.

In accordance with a second embodiment of the application, a reinforced catheter stock is provided for forming multiple catheters therefrom. The catheter stock includes a tubular member carrying a continuous coil reinforcement member thereon. First and second buildups of first and second material layers are disposed thereon wherein the first inner layer is softer than the second outer layer. The catheter stock may be cut into pieces to provide catheters having selected lengths as desired.

In the second embodiment of the application, the reinforced catheter stock 64 is provided for manufacturing reinforced catheters. The catheter stock 64 is constructed in accordance with a method as set out in the specification and shown in

flow chart form in Fig. 1. It is to be appreciated that selected method steps from Fig. 1 are illustrated in various drawing figures including Figs. 2a-2f. The end product resultant from the method shown in Fig. 1 is a reinforced catheter stock construction 64 as shown in Fig. 2f. More particularly, the reinforced catheter stock 64 (Fig. 2f) comprises a selected length of an elongate flexible tubular member 51 (Fig. 2a) defining a lumen of the catheter stock. The tubular member has a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock. A continuous coil reinforcement member 54 (Figs. 2b-2f) is carried on the elongate flexible tubular member 51 (Figs. 2b-2f) and extends from the lead end of the catheter stock to the trailing end of the catheter stock. A continuous outer coating of a first material 58 (Fig. 2e) covers the coil reinforcement member 54 and the tubular member substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. Further, a continuous outer coating of a second material 62 (Fig. 2f) covers the continuous outer coating of the first material 58 substantially entirely between the lead end of the catheter stock and the trailing end of the catheter stock. In the second embodiment of the invention, the first material 58 is softer than the second material 62.

Claims 1 and 3-11 are in Condition for Allowance:

As noted above, independent claim 1 and claims 6-11 dependent therefrom were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,972,143 to Stevens. This rejection is traversed for reasons set out below.

Independent claim 1 includes limitations not found in the Stevens '143 patent. The claim recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member carried on the flexible tubular member, and first and second outer coatings covering the coil reinforcement member, the first coating being softer than the second coating. The elongate flexible tubular member defines a lumen of the catheter and has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The continuous

coil reinforcement member is carried on the elongate flexible tubular member and extends from the proximal end of the catheter and terminates at the distal end of the catheter. The first outer coating covers the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating between a first transition area of the catheter and the proximal end of the catheter. A second portion of the first outer coating is uncovered by the second outer coating between the first transition area and the distal end of the catheter and defines a flexible distal tip of the catheter.

It is respectfully submitted that the prior art of record does not teach or suggest a construction of a reinforced catheter including a continuous coil reinforcement member extending from the proximal end of the catheter and terminating at the distal end of the catheter. More particularly, in the primary reference cited by the Examiner, namely, the Stevens '143 patent, it is respectfully submitted that there is no teaching of a reinforcement member extending into, at, or from the distal end or portion of the catheter. Rather, in the Stevens '143 patent, the reinforcement member is removed from the distal end of the catheter by grinding it away or otherwise removing it to provide a very flexible tip.

In the prior art Stevens '143 patent, the reinforcement member is not continuous from the proximal end of the catheter and terminating at the distal end. Simply, the distal end of Stevens '143 has no reinforcement member.

The limitation in the claim of "continuous" is clear, that is, the reinforcement member is uninterrupted and extends from the proximal end of the catheter and terminates at the distal end. Thus, the proximal end of the catheter is a starting point for the continuous reinforcement member to extend. In addition, the continuous coil reinforcement member recited in the claim extends to and terminates at the distal end of the catheter which means that it extends to the extremity of the catheter so as to reach the extremity.

Again, the primary art reference cited by the Examiner of the Stevens '143 patent shows a discontinuous reinforcement member which does not extend to the extreme distal end of the catheter. In addition, neither the Weber nor the Adams, et al. patent cited by the Examiner teach, suggest, or fairly disclose a continuous coil reinforcement member terminating at a distal end and first and second coatings wherein the first coating is softer than the second coating.

In addition to the above, it is respectfully submitted that the prior art of record does not teach or suggest a construction of a catheter including a continuous coil reinforcement member extending between the proximal and distal ends of the catheter and being coated by a first material and a second material wherein the first material is softer than the second material. More particularly, in the primary reference cited by the Examiner, namely the Stevens '143 patent, it is respectfully submitted that there is no teaching of first and second continuous flexible coatings covering a coil reinforcement member with the outer coating being harder than the inner coating. At best, in the Stevens '143 patent, the extruded thin coat is meant simply to adhere the braided steel reinforcement member onto the underlying tubular body. In addition to the above, nowhere in the Stevens '143 patent is there a teaching that the hardness of the bonding layer relative to the outer coating is of any significance. Still further, in the Stevens '143 patent, a portion of the stainless steel reinforcement member is ground away prior to the application of the single outer flexible coating. Thus, the reinforcement member in the prior art does not extend fully between the proximal end of the catheter and the distal end of the catheter. In addition, neither of the Weber nor Adams, et al. patents teach or suggest these limitations.

The above limitations are clearly recited in independent claim 1. The amendments to claim 1 above are for purposes of clarifying that the flexible distal tip of the subject catheter includes a coil reinforcement member, unlike the prior art teaching. For at least these reasons, it is respectfully submitted that independent claim 1 and claims 3-11 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 24 and 26-28 are in Condition for Allowance:

Independent claim 24 was rejected under 35 U.S.C. § 103(a) (based on a telephone conference with the Examiner) over U.S. Patent No. 5,972,143 to Stevens. The Examiner took the position that "Stevens discloses a reinforced catheter substantially as claimed however, it might not be clear whether or not the first material is softer than the second material" in the Office Action. This rejection is respectfully traversed because Stevens does not disclose a catheter substantially as claimed and for reasons set out below.

Independent claim 24 recites a reinforced catheter stock for manufacturing reinforced catheters. The catheter stock comprises a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the tubular member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock, a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the lead end of the catheter stock to the trailing end of the catheter stock a continuous outer coating of a first material covering the coil reinforcement member and the tubular member substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock; and, a continuous outer coating of a second material covering said continuous outer coating of said first material substantially entirely between said lead end of the catheter stock and the trailing end of the catheter stock, said first material being softer than said second material.

Again, it is respectfully submitted that the art of record does not teach or suggest a catheter stock for making a reinforced catheter having a continuous coil reinforcement member extending from one end of the catheter to the opposite end and having first and second outer coatings of first and second materials, respectfully, covering the coil reinforcement member wherein the outer coating is harder than the inner coating and a portion of the outer coating being selectively removable from the inner coating to expose a soft distal tip portion of the catheter.

The Examiner has misconstrued the Stevens '143 patent. More particularly, attention is invited to Figures 2a-2f of the Stevens '143 patent whereat a catheter stock construction sequence is illustrated. Figure 2a shows a first layer 10 deposited onto a mandrill and in Figure 2b a braided reinforcement member is wrapped thereon. In Figure 2c, a plurality of spaced apart bonding layer portions are provided 14, 16, 18 so that selected spaced apart portions of the reinforcement wire can be removed by a grinding process without causing fraying to occur in the reinforcement wire. As shown in Figure 2d, the reinforcement wire is selectively ground away from the structure at locations 30, 32, and 34 to provide a discontinuous reinforcement member along the length of the catheter stock. Thereafter, one or more outer cover layers are deposited onto the discontinuous formations of the braided reinforcement member.

The reinforced catheter stock recited in independent claim 24 clearly includes the limitation of a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the head end of the catheter stock to the trailing end of the catheter stock. The reinforcement member taught in the Stevens '143 patent, however, is clearly discontinuous as shown in Figure 2d. In the Stevens '143 patent, the outer coating layers are applied after the discontinuity is created in the reinforcement member. In the construction recited in independent claim 24, however, the coil reinforcement member is continuous and is covered by outer coatings of first and second materials.

Neither the Weber or Adams, et al. patents teach, suggest, or fairly disclose a reinforced catheter stock for use in manufacturing multiple catheter devices. Rather, each of those patents teach individual catheters having various features thought to be interesting to the Examiner. None, however, teach a reinforced catheter stock.

For at least the above reasons, it is respectfully submitted that independent claim 24 as amended above and claims 26-28 dependent therefrom are patentable distinct and unobvious over the art of record.

Claims 41-51 are in Condition for Allowance:

Independent claim 41 and claims 42 and 43 dependent therefrom were rejected under 35 U.S.C. § 103(a) (according to a telephone conversation with the Examiner) over U.S. Patent No. 5,972,143 to Stevens. Dependent claims 44-51 were rejected under the same statute section as being unpatentable over the Stevens '143 patent in view of U.S. Patent No. 4,832,023 (according to a telephone conversation with the Examiner) to Murphy-Chutorian. This rejection is respectfully traversed for reasons set out below.

Independent claim 41 recites a reinforced catheter comprising an elongate flexible tubular member, a first outer coating covering the tubular member, a second flexible outer coating covering a first portion of the first outer coating, and a coil reinforcement member carried on the elongate flexible tubular member and disposed at a distal tip of the catheter. The elongate flexible tubular member defines the lumen of the catheter and includes a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The first flexible outer coating covers the tubular member fully between the proximal end of the catheter to the distal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating at the proximal end of the catheter while a second portion of the first outer coating remains or is otherwise uncovered by the second outer coating at the distal end of the catheter and defines a flexible distal tip of the catheter. In the catheter of claim 41, the first coating is softer than the second coating.

As noted above in connection with the prior art cited by the Examiner, U.S. Patent No. 5,972,143 to Stevens teaches a catheter including a coiled reinforcement member covered in a practical sense by only a single flexible outer coating. The coil reinforcement does not extend the entire length of the catheter but, however, is removed from a distal tip portion thereof.

Independent claim 41 recites a catheter having a coil reinforcement member disposed at a distal tip portion thereof. This is, of course, contrary to the teachings of the Stevens '143 patent which, as noted above, includes a coil

reinforcement member in a portion of the catheter but the coil member is removed from the distal tip portion thereof.

For at least the above reasons, applicant respectfully submits that independent claim 41 and claims 42-51 dependent therefrom are patentably distinct and unobvious over the art of record.

Claims 52-60 are in Condition for Allowance:

Applicant has added new independent claim 52 together with dependent claims 53-60. It is respectfully submitted that the prior art of record does not teach or suggest the novel reinforced catheter construction recited in independent claim 52 and including the additional limitations added to claim 52 by way of dependent claims 53-60. Independent claim 52 recites a reinforced catheter comprising an elongate flexible tubular member, a continuous coil reinforcement member, and first and second flexible outer coatings. The elongate flexible tubular member has a first end and a second end and defines a lumen of the catheter. The continuous coil reinforcement member is on the elongate flexible member and terminates at the first and second ends of the tubular member. The first flexible outer coating covers the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member. The second flexible outer coating covers a first portion of the first outer coating from a first transition area of the catheter and terminates at the first end of the tubular member. A second portion of the first outer coating is uncovered by the second outer coating and defines a flexible distal tip of the catheter from the first transition area and terminating at the second end of the tubular member. Lastly, the first coating is softer than the second coating.

Again, based upon prosecution of the instant application to date, the primary art reference cited by the Examiner of the Stevens '143 patent shows a discontinuous reinforcement member which does not have termination points at the first and second ends of the tubular member defining the catheter. In addition, none of the art of record cited by the Examiner teaches such a reinforcement member on first and

second outer coatings forming a catheter construction as defined in claim 52 wherein the first coating is softer than the second coating. Claims 53-60 add further limitations to patentable independent claim 52.

For at least the above reasons, it is respectfully submitted that independent claim 52 as well as claims 53-60 dependent therefrom are patentably distinct and unobvious over the references of record.

Claims 61-64 are in Condition for Allowance:

Applicant has added new independent claim 61 and dependent claims 62-64. Independent claim 61 is directed to a reinforced catheter comprising an elongate flexible tubular member, first and second flexible outer coatings, and a coil reinforcement member. The elongate flexible tubular member defines a lumen of the catheter and has a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. The first flexible outer coating covers the tubular member completely from the distal end of the catheter to the proximal end of the catheter. The second flexible outer coating covers a first portion of the first outer coating at the proximal end of the catheter. A second portion of the first outer coating at the distal end of the catheter is uncovered by the second outer coating and defines a flexible distal tip of the catheter. The first coating is softer than the second coating. The coil reinforcement member of the catheter is carried on the elongate flexible tubular member and is disposed at the distal tip of the catheter.

It is respectfully submitted that none of the prior art of record teaches, suggests, or fairly discloses a construction of a reinforced catheter of the type recited in independent claim 61. Again, the primary art reference cited during prosecution by the Examiner of the Stevens '143 patent shows a discontinuous reinforcement member which does not extend to the distal end of the catheter. Clearly, in independent claim 61, the coil reinforcement member is carried on the elongate flexible tubular member and is disposed at the distal tip of the catheter. Further, in independent claim 61, the first coating is softer than the second coating and a portion of the first flexible outer

coating is uncovered by the second outer coating and defines the flexible distal tip of the catheter. None of the art of record, alone or in combination, teaches or suggests such a construction.

For at least the above reasons, it is respectfully submitted that independent claim 61 and claims 62-64 dependent therefrom are patentably distinct and unobvious over the references of record.

Claim 65 is in Condition for Allowance:

Applicant has added new independent claim 65 which is directed to a reinforced catheter including an elongate flexible tubular member, a continuous coil reinforcement member, and first and second flexible outer coatings. The elongate flexible tubular member has a first end and a second end and defines a lumen of the catheter. The continuous coil reinforcement member is on the elongate flexible tubular member and terminates at the second end of the tubular member. The first flexible outer coating covers the coil reinforcement member and the tubular member substantially entirely between the first end and the second end of the tubular member. The second flexible outer coating covers a first portion of the first outer coating from a first transition area of the catheter and terminates at the first end of the tubular member. A second portion of the first outer coating is uncovered by the second outer coating and defines a flexible tip of the catheter from the first transition area and terminates at the second end of the tubular member. In the reinforced catheter of claim 65, the first coating is softer than the second coating.

Again, the primary art reference cited during prosecution by the Examiner of the Stevens '143 patent shows a discontinuous reinforcement member which does not terminate at the second end of the tubular member forming the reinforced catheter. In addition, the other references of records cited by the Examiner do not teach, suggest, or fairly disclose a continuous coil reinforcement member terminating at a second end of a tubular member and first and second outer coatings, the second outer

coating covering a portion of the first outer coating and the first coating being softer than the second coating.

For at least the above reasons, it is respectfully submitted that new independent claim 65 is patentably distinct and unobvious over the art of record.

CONCLUSION

In view of the above amendments, comments, and arguments presented, it is respectfully submitted that all pending claims are patentably distinct and unobvious over the references of record.

Allowance of all pending claims and early notice to that effect is respectfully requested.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & MCKEE, LLP

16 MAY 06
Date

Michael E. Hudzinski
Michael E. Hudzinski, Reg. No. 34,185
1100 Superior Avenue, Seventh Floor
Cleveland, OH 44114-2579
216-861-5582

CERTIFICATE OF MAILING OR TRANSMISSION

Under 37 C.F.R. § 1.8, I certify that this Amendment B and Response is being

- ☒ deposited with the United States Postal Service as First Class mail, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.
- ☐ transmitted via facsimile in accordance with 37 C.F.R. § 1.8 on the date indicated below.
- ☐ deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Express Mail Label No.:	Signature <u>Barbara Brazier</u>
Date May 10, 2006	Printed Name Barbara Brazier

N:\RSTZ\200011\3A\bjb0004574V001.doc